

REMARKS/ARGUMENTS

Claims 1, 9 and 14 have been revised to recite the inherent feature of 5T4 expression as indicative of “stem cells which have activated the differentiation pathway” as recited on page 3, lines 30-31, and as supported by page 4, lines 15-19, and page 7, lines 1-2, of the instant application and by claim 8.

Claim 2 has been revised to recite the inherent feature of the “absence or lack of 5T4 expression [as] no 5T4 expression or a low or negligible level of 5T4 expression” as recited on page 4, lines 16-18 of the instant application as well as the previous language in claim 2. Claim 2 has also been revised to remove the redundant language.

These revisions to the claims raise no new matters for search or consideration as they simply represent the same claimed subject matter with alternative language. No new matter has been introduced, and entry of the above revised claims is respectfully requested.

Specification

Applicants acknowledge the holding in abeyance of the requirement for a new title “that is indicative of the invention to which the claims are directed”. Applicants understand that the abeyance is provided pending determination of the final language of the claims during prosecution.

Alleged issue under 35 U.S.C. §112, First Paragraph

Claims 1-6, 8-10, and 14 were rejected under 35 U.S.C. §112, first paragraph, as allegedly not enabled such that a skilled artisan could make and/or use the invention beyond the scope of “mouse embryonic stem (mES) cells or human embryonic carcinoma (hEC) cells”. Applicants have carefully reviewed the statement of the rejection in the Action, mailed December 13, 2006, which statement does not include a re-establishment of a *prima facie* case against the claims as revised with the last response. Stated differently, there is no presentation of a *prima facie* case against the revised claims.

The statement of the rejection appears to be based upon the position that “the absence of 5T4 antigen indicates undifferentiated or pluripotent stem cells” (see paragraph bridging pages 3-4 of the Action) and that:

until it is demonstrated that ES cell that are negative for 5T4 antigen can differentiate into other cell types and express the 5T4 antigen in the new tissue cell type, 5T4 antigen can not be considered a marker for differentiation as claimed. The expression patterns for 5T4 antigen are merely descriptive and identify a candidate stem cell marker (see paragraph bridging pages 6-7 of the Action).

But these statements appear to reflect a different position from that in the Advisory Action, mailed March 21, 2007. According to the comments therein, the instant rejection appears to be based upon the view that “for a cell to be considered truly differentiated, it must be demonstrated that the stem cell has lost its pluripotency or multipotency.” The rejection also appears to require the specification to disclose cells “that express 5T4 antigen have also lost pluripotency or multipotency.”

Applicants respectfully submit that each of the above positions reflect a fundamental misunderstanding of the claimed invention. The misunderstanding in the statement of the rejection (the first position) has been pointed out in the previous response, filed February 13, 2007, and addressed in the Advisory Action. Applicants turn now to the misunderstanding in the Advisory Action (the second position) as follows.

Contrary to the allegations in the Advisory Action, the claims are not directed to detecting the expression of 5T4 antigen in a stem cell as an indication of a complete “loss of pluripotency or multipotency”. A review of the language of claims 1, 2, 8, 9, and 14 shows that the idea of a “loss of pluripotency or multipotency” is in error, because the claims include the feature of identifying cells that are undergoing differentiation. This feature is not that of a complete or total “loss of pluripotency or multipotency” as alleged in the Advisory Action. This same concept was intended by the previously offered “differentiated cells” term, which meant

cells that had differentiated to some degree, as opposed to completely or totally differentiated cells that could not differentiate further.

As found in the claims, the concept of cells that are undergoing differentiation, as opposed to cells that are undifferentiated, is understood and known to the skilled person in the field. Therefore, the emphasis on a demonstration that cells expressing 5T4 “have also lost pluripotency or multipotency” is misplaced.

Additionally, Applicants point out that the emphasis in the Advisory Action that “an artisan would not know if the expression of 5T4 antigen truly indicates that the cells are differentiated” also is misplaced, because the claims do not require such a “true indication”. Instead, the claims are directed to an indication of some degree of differentiation, and there is no objective basis provided to doubt that 5T4 antigen expression is indicative of a cell undergoing differentiation, such as a stem cell that is no longer undifferentiated.

In light of the above discussion, Applicants respectfully submit that no *prima facie* case of non-enablement is present, and this rejection is misplaced against the pending claims. Therefore, this rejection may be properly withdrawn.

Alleged issue under 35 U.S.C. §112, Second Paragraph

Claim 2 was rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for recitation of “low or negligible”, which is asserted in the statement of the rejection as rendering the claim indefinite.

Applicants respectfully point out that no *prima facie* case of indefiniteness has been presented, because the interpretation of “low or negligible” appears to have been made without adequate consideration of the applicable standards regarding permissible claim breadth.

Nevertheless, claim 2 has been revised with alternative language supported at least on page 4, lines 16-18, of the instant application. Applicants respectfully submit that with the revision, no issue remains and that this rejection may be withdrawn.

Claims 1-6 and 14 were also rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for recitation of “reflects”, which is asserted in the statement of the rejection as rendering the claims indefinite.

Applicants respectfully point out that no *prima facie* case of indefiniteness has been presented, because the interpretation of “reflects” appears to have been made in a vacuum without consideration of the claim context in which the language occurs and without consideration “in light of the specification”.

Nonetheless, claims 1 and 14 have been revised with alternative language supported at least on page 3, lines 30-31 of the instant application. Applicants respectfully submit that with the revision, no issue remains and that this rejection may be withdrawn.

Alleged issues under 35 U.S.C. §102

Claims 1, 3, 8, and 14 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Southall et al. Applicants have carefully reviewed the statement of the rejection and respectfully traverse because once again, no *prima facie* case of anticipation has been presented.

As an initial matter, Applicants point to a statement on page 10 of the Action mailed December 13, 2006:

This rejection was intended to demonstrate the breadth of the claims
and that it encompasses subject matter not intended in the instant
invention.

The above statement appears to indicate the Office’s understanding that the claimed subject matter does not relate to “carcinoma cells”. This is consistent with a reading of the claims “in light of the specification” as required under well settled law. But given this proper understanding of the claims, the instant rejection nevertheless asserts that the claims encompass “carcinoma cells.” Thus the rejection appears to be mistakenly based upon an incorrect interpretation of the claims.

The erroneous basis of the rejection is clearly seen with respect to claim 8, which recites “wherein binding of the anti-5T4 antibody to cells in the sample is indicative of the presence of 5T4 and *differentiated* stem cells” (italics added). But this is also clearly opposite from the disclosure by Southall et al., who report on work with carcinoma cells that express 5T4 and are acknowledged in the statement of the rejection as “undifferentiated”.

This distinction between the claimed subject matter and Southall et al. is also present in the remaining claims, which have been revised in the interest of advancing prosecution of the instant application and without acquiescence to the instant rejection. Therefore, claims 1 and 14 have been revised to include the inherent features of 5T4 expression as indicative of cells undergoing differentiation as opposed to cells that are undergoing “de-differentiation.” This is particularly relevant with respect to claim 2, where the absence of 5T4 expression is indicative of undifferentiated cells. These features are clearly supported by the content of the instant application, such as on pages 3, 4, and 7 as representative examples.

Given the clearly opposing concepts between the claimed subject matter and the Southall et al. document, Applicants respectfully submit that Southall et al. cannot anticipate the instantly rejected claims. Therefore, this rejection may be properly withdrawn.

CONCLUSION

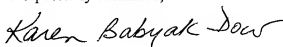
In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

Appl. No. 10/520,502
Amdt. dated May 10, 2007
Response Under 37 C.F.R. 1.114 Request for RCE
Examining Group 1632

PATENT

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 858-350-6100.

Respectfully submitted,

A handwritten signature in cursive script that reads "Karen Babyak Dow".

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